

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

	)	<b>MDL No. 1456</b>
<b>IN RE PHARMACEUTICAL INDUSTRY</b>	)	<b>Master File No. 01-12257-PBS</b>
<b>AVERAGE WHOLESALE PRICE LITIGATION</b>	)	
<hr/>	)	<b>Judge Patti B. Saris</b>
	)	
<b>THIS DOCUMENT RELATES TO:</b>	)	
<b>State of California, <i>ex rel.</i> Ven-A-Care v.</b>	)	
<b>Abbott Laboratories, <i>et al.</i></b>	)	
<b>03-CV-11226-PBS</b>	)	
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**PLAINTIFFS' OBJECTIONS PURSUANT TO RULE 201(e) OF THE  
FEDERAL RULES OF EVIDENCE TO JUDICIAL NOTICE OF FACTS AND  
CONCLUSIONS SET FORTH IN DEFENDANTS' MOTION TO DISMISS**

In their Memorandum of Law in Support of Their Motion to Dismiss the First Amended Complaint-In-Intervention (Defendants' Joint Motion, or "DJM"), Defendants attach as exhibits a fraction of the public record and, based on a misleading and selective reading of the same, assert this Court should take judicial notice of several allegedly adjudicative facts. Attempting to buttress their Background section and to create a basis for one of their Rule 12(b)(6) arguments, Defendants request judicial notice of the Department of Health Services' and/or the Legislature's purported knowledge that reported prices often exceeded providers' actual acquisition prices.

DJM 1-2, 8-11, 22-24. On that basis, Defendants urge the Court to find - - on a motion to dismiss - - that California knowingly and deliberately reimbursed for pharmaceutical products at levels far in excess of providers' acquisition costs, for "political" reasons, the substance of which

is never explained.

Pursuant to Rule 201(e) of the Federal Rules of Evidence, Plaintiffs object to taking judicial notice of disputed adjudicative facts, as well as Defendants' unsupported conclusions, and request the opportunity to be heard on these objections. *See* Fed. R. Evid. 201(e) ("A party is entitled upon timely request to an opportunity to be heard as to the propriety of taking judicial notice and the tenor of the matter noticed."). A judicially noticeable fact must be one "not subject to reasonable dispute," either because it is "(1) generally known within the territorial jurisdiction of the trial court or (2) [is] capable of accurate and ready determination by resort to sources whose accuracy cannot readily be questioned." Fed. R. Evid. 201(b). Defendants have failed to either adequately recognize or satisfy this robust standard, which requires "a high degree of indisputability" concerning either Defendants' purportedly adjudicative facts or the associated conclusions they urge this Court to draw. *See* Fed. R. Evid. 201, advisory committee's note to subdivision (a).

Judicial notice is also improper because Defendants cannot show that their proposed adjudicative facts and conclusions are relevant. *See* 1 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence* § 201.30[1] (2d ed., 1997). As set forth in Plaintiffs' Opposition to Defendants' Motion to Dismiss (Opp.), mere knowledge by the government – as opposed to fully informed approval – is not a defense to a false claims action. Opp. at 2-6. Accordingly, this Court should decline to take judicial notice of Defendants' proposed adjudicative facts and conclusions.

The implications of Defendants' improper request for judicial notice, if not appropriately denied by this Court, are significant. At their core, Plaintiffs allege that Defendants have

defrauded California by engaging in a complex, pervasive, and sophisticated scheme to misrepresent drug prices which are then used by California to reimburse Medicaid providers. At this early stage of the case, Defendants' would have the Court deny Plaintiffs any opportunity at all, either in a dispositive motion or at trial, from presenting evidence in support of the allegations in the First Amended Complaint. Defendants should not be permitted to achieve this result.

### ARGUMENT

#### **I. RULE 201(b) DOES NOT PERMIT JUDICIAL NOTICE OF DISPUTED FACTS DISCUSSED IN THE CONTENTS OF A PUBLIC RECORD.**

Defendants' discussion and legal argument in support of judicial notice is relegated to a single footnote in which they cursorily mention the single observation that the Court may take judicial notice of public records on a Rule 12(b)(6) motion. DJM 9 n. 4. This "analysis" ignores the key requirement of Rule 201(b), namely that the "judicially noticed fact must be one not subject to reasonable dispute." This requirement applies even when the document relied on is a public record. *See Lee v. Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001); *see also Carley v. Wheeled Coach*, 991 F.2d 1117, 1126 (3rd Cir. 1993); 1 *Weinstein's Federal Evidence* § 201.13[1][c].

#### **A. Disputed Facts Appearing in the Contents of Selected Documents Should Not Be Resolved By Judicial Notice.**

There is a significant difference between taking judicial notice of the existence of a public record, and taking judicial notice of its contents. For example, a court may take judicial notice of the existence of another court's opinion, but it will generally not take judicial notice of the truth of the facts set forth therein. *See Lee*, 250 F.3d at 690. The same is true of government reports.

*See id.*; *see also United States v. Bonds*, 12 F.3d 540, 553 (6th Cir. 1993). In *Lee*, the District Court erred in taking judicial notice of the “fact the government conducts numerous crash worthiness tests” and thereby concluding that the government was “as aware” as the defendant manufacturer of the vehicles’ rollover propensities. *See Lee*, 250 F.3d at 690. In another example, in *Carley*, the District Court erred in taking judicial notice of plaintiff’s “knowing waiver” of his right to contest extradition, even though the public record contained a signed waiver and sworn testimony from a prior hearing. *Carley*, 991 F.2d at 1126. Only when the fact contained in the document is indisputable, is judicial notice possible. In the case cited by Defendants, *In re Veritex Pharmaceuticals, Inc.*, 357 F.Supp.2d 343, 352 (D. Mass. 2005), this Court took judicial notice of the indisputable existence of an FDA policy appearing within the public record.

Here, Defendants misleadingly use limited statements from the public record to draw the far broader conclusion that California knowingly and willingly paid inflated prices. DJM 1-2, 8-11, 22-24. As in *Lee* and *Carley*, these are disputed factual issues that are not fully answered by the contents of the documents and, therefore, should not be resolved by judicial notice. As discussed below, Defendants’ characterization of the exhibits and their conclusions are plainly disputed.

**B. Plaintiffs Dispute The Selective Reading and Significance of Defendants’ Exhibits.**

Read in full, Defendants’ exhibits are subject to several reasonable interpretations which contradict Defendants’ proffered conclusions.<sup>1</sup> For example, exhibit A, the Federal audit and the

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<sup>1</sup> Further, at this preliminary 12(b)(6) motion stage, the Court does not have before it the full factual record, including contrary evidence. As a general matter, it is improper for courts to take judicial notice of

letter from a California Deputy Director, which Defendants argue demonstrates that California knowingly pays more for drugs than providers' actual costs, arguably suggests a lack of certainty about pricing, as the audit was investigating that very subject, as well as a concern about pricing discrepancies. This reasonable alternative interpretation hardly suggests the fact of a "knowing acceptance" of inflated prices.

Exhibit D is simply a memorandum by one public official in support of a requested action. The memorandum does not support the purported facts asserted by Defendants: that "California's MAIC program, which caps the maximum amount that Medi-Cal will reimburse for most generic drugs, has been in effect since at least the mid-1970's." DJM at 8. The memorandum does not even address the point whether MAICs capped *most* generic drugs, and the full record will in fact establish that MAICs did not cap the reimbursement for most of the generic drugs at issue in the First Amended Complaint in Intervention (FAC).

Exhibit E is a price list from a time period not covered by Plaintiffs' Complaint. Defendants argue these price lists show California's purported knowledge. DJM 9. However, these price lists significantly pre-date the allegations of the complaint, and therefore, are irrelevant as to the alleged false claims. Defendants' exhibits do not show that during the period from 1994 to date California: (i) was given timely, ready and regular access to provider pricing; (ii) always knew which manufacturers and which drugs were creating spreads and by how much; or (iii) agreed to the excessive spreads. Defendants err by asking this Court to draw broad conclusions based on limited and inapplicable facts. *See, infra*, Part I.C.

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supposed facts if credible contrary evidence exists. *Rivera-Torres v. Ortiz Velez*, 341 F.3d 86, 101 (1st Cir. 2003) (refusing to take judicial notice *at trial* of Puerto Rican law regarding government appointments because did not always correspond to realities of government practice).

Defendants rely on Exhibit G, entitled “State Strategies to Contain Medicaid Drug Costs,” for the sweeping assertion that “[i]n sum, like so many other states, California has long known that it reimbursed providers substantially more than what the providers paid to acquire Defendants’ drugs. And like other states, California did so as a result of political factors or to ensure provider participation in Medi-Cal.” DJM 11. However, Exhibit G nowhere states that California - - or any other states - - knew the spreads of the named defendants for the identified drugs, nor determined that those spreads were acceptable to California for political reasons. To the contrary, the report speaks of the “obfuscation of price by drug manufacturers” and the lack of “alternative sources for drug prices.” Ex. G at 9.<sup>2</sup> Throughout, Defendants present only a fraction of the public record and give that fraction a reading that masks Plaintiffs’ disputes with the adjudicatory facts and conclusions in Defendants’ Rule 12(b)(6) motion.

**C. Judicial Notice of Broad Conclusions Based on Limited Evidence is Disfavored.**

In general, the courts decline to take judicial notice of sweeping conclusions based on a limited presentation of facts. *See United States v. Hoyt Cinemas Corp.*, 380 F.3d 558, 570 (1st Cir. 2004) (rejecting district court’s judicial notice of a single theatre patron seating preference given the variety of theatre configurations and lack of evidence); *see also New Alliance Party v. N.Y. State Bd. of Elections*, 861 F. Supp. 282, 292 (S.D.N.Y. 1994) (Ballot position bias’ “imprecise and conditional nature preclude it from being characterized as a judicially noticed

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<sup>2</sup> In addition, Defendants’ citation to Relator’s Complaint as a document of which the Court may take judicial notice is patently incorrect, other than the fact of its existence. That Complaint is not a public record. *See* Fed. R. Evid. 803(8). Moreover, Defendants presumably would be the last to argue that this Court should take judicial notice of the facts within the Relator’s sealed allegations. The fact that those allegations were brought to the attention of the Attorney General, who is required to undertake an investigation of such sealed allegations to verify their substance, does not warrant taking judicial notice of the conclusory assertion that the State was required – or even permitted – to accept them as true.

fact”). Here, similar forbearance by the Court is appropriate. Defendants want this Court to dismiss Plaintiffs’ false claims allegations regarding millions of reimbursements on hundreds of Defendants’ drugs over a period stretching back to 1994, *see* FAC Exhs A -H, J, K, M-O, based on a broad and insufficient assertion of purported generalized government knowledge. The use of judicial notice on a motion to dismiss should not substitute for the development of a full factual record.

## **II. CONCLUSIONS DRAWN FROM EVIDENCE OF LEGISLATIVE INACTION ARE INHERENTLY DISPUTABLE.**

Presupposing government knowledge, Defendants proceed to lay the blame for payment of the false claims they caused on the Legislatures’ doorstep. DJM 1, 10-11. As a matter of law, Defendants far-reaching assertion of general “consent” to inflated pricing must be rejected because it rests on the flawed theory of “legislative inaction.” The courts have consistently cautioned against drawing inferences from the failure of a legislative or regulatory body to act. *E.g., United States v. Craft*, 535 U.S. 274, 287 (2002) (“congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction”). Courts “walk on quicksand when [they] try to find in the absence of corrective legislation a controlling legal principle.” *Central Bank of Denver, N.A. v. First Inter-State Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994); *see also Arnold Tours, Inc. v. Camp*, 472 F.2d 427, 437 (1st Cir. 1972) (“Congressional inaction frequently betokens unawareness, preoccupation, or paralysis”) (citation omitted); *Commonwealth v. Houston*, 430 Mass. 616, 630, 722 N.E. 2d 942 (Mass 2000) (“Ascertaining meaning from the Legislature’s decision not to enact statutory language, however, is an uncertain endeavor”).



## CONCLUSION

Defendants' request to have this Court take judicial notice of their exhibits and the misleading conclusions they draw from those documents must be rejected in its entirety. The standards erected under Rule 201 of the Federal Rules of Evidence establish a bar which Defendants have failed to address and cannot satisfy as a matter of law. Rule 201 does not allow judicial notice of the disputed adjudicatory facts proffered by Defendants under the guise of judicial notice.

Respectfully submitted,  
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Dated: March 2, 2006

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**CERTIFICATION PURSUANT TO LOCAL RULE 7.1**

I certify that the moving party has communicated with counsel for Defendants in an effort to resolve the dispute referred to in this motion, and that the parties have not been able to reach agreement with respect thereto.

Dated: March 2, 2006

/s/ Nicholas N. Paul  
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Supervising Deputy Attorney General

**CERTIFICATE OF SERVICE**

I, Nicholas N. Paul, hereby certify that on March 2, 2006, I caused a true and correct copy of the foregoing, **PLAINTIFFS' OBJECTIONS PURSUANT TO RULE 201(e) OF THE FEDERAL RULES OF EVIDENCE TO JUDICIAL NOTICE OF FACTS AND CONCLUSIONS SET FORTH IN DEFENDANTS' MOTION TO DISMISS** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: March 2, 2006

/s/ Nicholas N. Paul  
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